

REMARKS

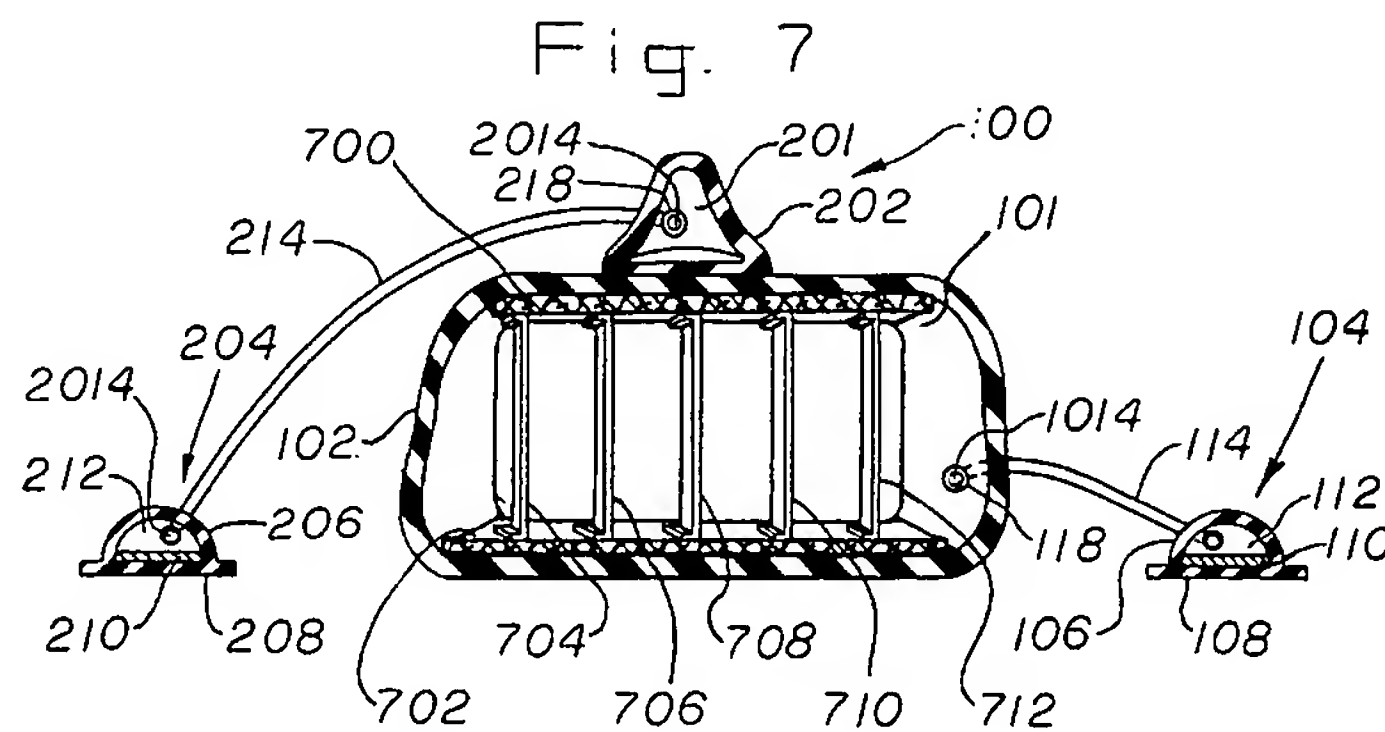
The above-identified application has been reviewed in light of the Office Action mailed March 15, 2005. By the present amendment, the Applicant has amended claims 15-21, has canceled claim 22, and added new claim 26. Claims 23-25 were withdrawn by the Examiner as being directed towards a non-elected species. It is respectfully submitted that the claims pending in the application do not introduce new subject matter, are fully supported by the specification, and are patentable over the prior art. Prompt and favorable consideration of these claims is earnestly sought.

The Office Action rejected claims 15-22 under 35 U.S.C. § 112 as being indefinite. In particular, it was asserted that the meaning of the term "non-uniform shape" is unclear. In the interest of furthering prosecution of the present application, the Applicant has amended claim 15 to remove the recitation of the term "non-uniform shape" and recite specific shapes of the inflatable bladder. Therefore, it is respectfully requested that the rejection of claims 15-22 be withdrawn.

The Office Action rejected claims 15-18, 20, and 22 under 35 U.S.C. § 102 (b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103 (a) as obvious over U.S. Patent No. 4,651,717 to Jakubczak (the '717 patent). According to the Office Action, the '717 patent discloses a shaft 214 and an inflatable bladder 201 having a non-uniform (i.e. conical) shape when inflated (see Figure 7 reproduced below). In addition, it was asserted that the device of the '717 patent is a retractor since it moves tissue or, alternatively, it would have been obvious that the device of the '717 patent is a retractor since it moves tissue.

As presently amended, independent claim 15 recites, *inter alia*, an apparatus including a shaft and "an inflatable bladder disposed at the distal end of the shaft" wherein "the inflatable bladder, upon inflation, is capable of separating adjacent layers of tissue thereby creating a working space, and has a shape selected from the group consisting of: eccentric, conical, and wedge-shaped."

The '717 patent relates to a device having one or more inflatable bladders adapted for reconstructive plastic surgery and is adapted to expand soft tissue in preparing a space for an implantable mammary prosthesis. The '717 patent discloses that the device 100 includes an inflatable bladder 202 coupled to a hollow tube 214. The inflatable bladder 202 and the hollow tube 214 are formed from a biocompatible silicone elastomer (see '717 patent Column 4, lines 60-68 and Column 3, lines 47-49, respectively). The '717 patent discloses that the device 100 includes inflatable balloons having generally hemispherical shapes.



The '717 patent does not disclose or suggest a device including, *inter alia*, an apparatus including a shaft and "an inflatable bladder disposed at the distal end of the shaft" wherein "the inflatable bladder, upon inflation, is capable of separating adjacent layers of tissue thereby creating a working space, and has a shape selected from the group consisting of: eccentric, conical, and wedge-shaped" as recited in amended claim 15.

Therefore, it is respectfully submitted that amended claim 15 is not anticipated or suggested by the '717 patent and the rejection of the Office Action has been overcome. Claims 16-18 and 20 depend directly or indirectly from amended independent claim 15 and it is respectfully submitted that these claims are also allowable over the '717 patent.

In the Office Action, claims 15, 17-20, and 22 were rejected under 35 U.S.C. § 102 (e) as anticipated by or, in the alternative, under 35 U.S.C. § 103 (a) as obvious over U.S. Patent No. 4,921,478 to Solano et al. (the '478 patent). According to the Office Action, the '478 patent discloses a shaft 22 and an inflatable bladder 16 which has the non-uniform shape of a wedge when inflated since it tapers in the distal direction (see Figure 5C reproduced below). It was also asserted that the device of the '478 patent is a retractor since it moves tissue or, alternatively, it would have been obvious that the device of the '478 patent is a retractor since it moves tissue.

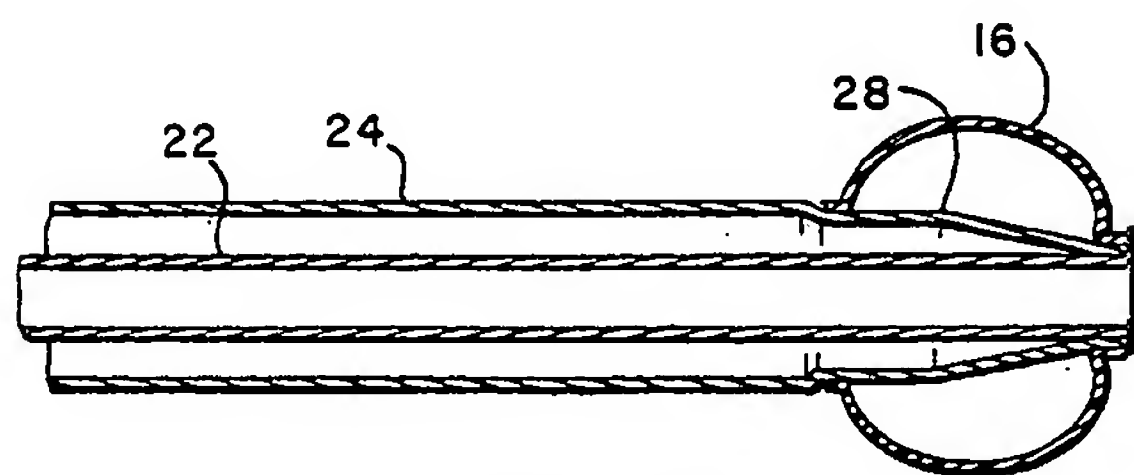


Fig. 5A

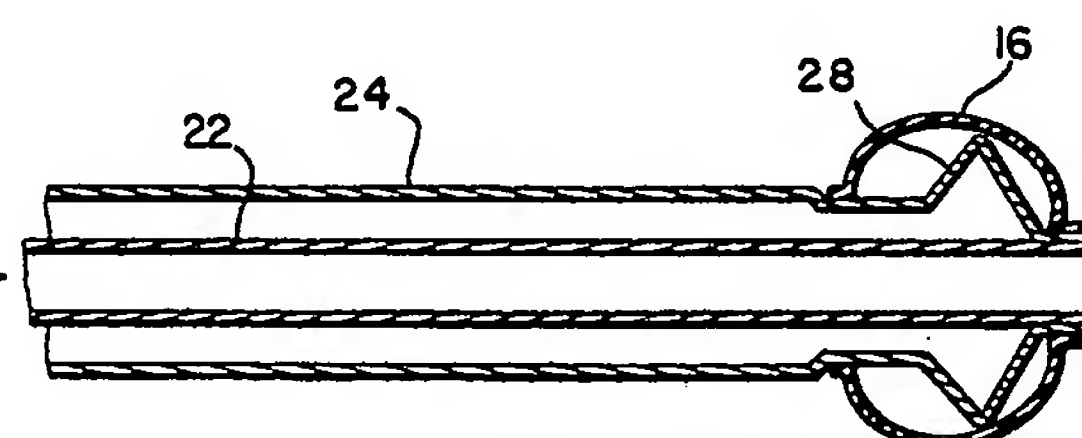


Fig. 5B

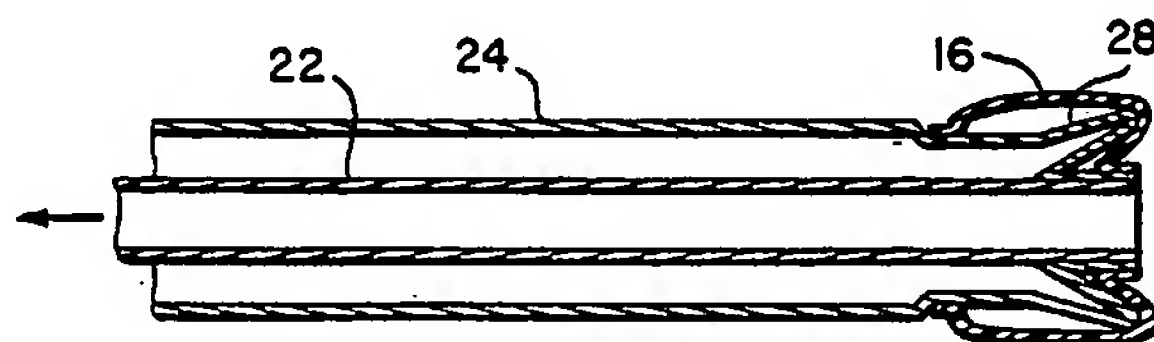


Fig. 5C

The Office Action rejected claim 21 under 35 U.S.C. § 103 (a) as obvious over the '478 patent. According to the Office Action, the '478 patent fails to disclose using a cannula and asserted that it is old and well known to use a cannula when inserting a catheter in the body and that it would have been obvious to combine the device of the '478 patent with a cannula.

As presently amended, independent claim 15 recites, *inter alia*, an apparatus including "a shaft having open proximal and distal ends defining a lumen therethrough" and "an inflatable bladder disposed at the distal end of the shaft and in fluid communication with the lumen, wherein the inflatable bladder, upon inflation, is capable of separating adjacent layers of tissue thereby creating a working space, and has a shape selected from the group consisting of: eccentric, conical, and wedge-shaped"

The '478 patent relates to a balloon angioplasty system having inner and outer shafts 22, 24, and inflatable balloon 16. The inner shaft 22 has open proximal and distal ends defining an inner lumen that extends therethrough (see the '478 patent at Column 5, lines 2-5) and allows fluids and debris to be flushed from the body through the lumen (see the '478 patent Column 1, lines 55-58). According to the '478 patent, the inflatable balloon 16 is circumferentially attached around a distal portion of the outer shaft 24 such that, either in an uninflated state or in an inflated state, balloon 16 does not cover the open distal end of the inner shaft 22 so that fluids and debris may pass through the inner lumen of inner shaft 22. The '478 patent does not disclose or suggest a device including "a shaft having open proximal and distal ends defining a lumen therethrough" and "an inflatable bladder disposed at the distal end of the shaft and in fluid communication with the lumen, wherein the inflatable bladder, upon inflation, is capable of separating adjacent layers of tissue thereby creating a working space, and has a shape selected

from the group consisting of: eccentric, conical, and wedge-shaped" as recited in amended claim 15. Moreover, attaching an inflatable balloon "at the distal end of the shaft," as recited in amended claim 15, would be contrary to the disclosure of the '478 patent and render the disclosed device unsuitable for its intended purpose.

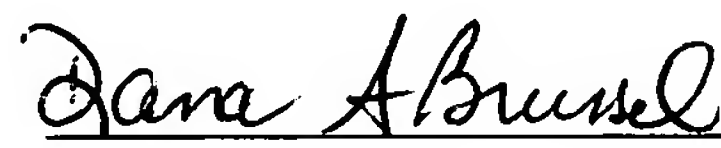
As discussed hereinabove, the '478 patent discloses a device having an inner shaft 22 defining an inner lumen therethrough for allowing fluids and debris to exit the body through the inner lumen. Disposing an inflatable balloon "at the distal end of the shaft" would block the opening of the inner lumen and render the device unsuitable for its intended purpose. Therefore, it is respectfully submitted that the '478 patent does not anticipate or suggest a device including, *inter alia*, "a shaft having open proximal and distal ends defining a lumen therethrough" and "an inflatable bladder disposed at the distal end of the shaft and in fluid communication with the lumen, wherein the inflatable bladder, upon inflation, is capable of separating adjacent layers of tissue thereby creating a working space, and has a shape selected from the group consisting of: eccentric, conical, and wedge-shaped" as recited in amended claim 15. Claims 17-20 depend directly or indirectly from amended independent claim 15 and it is respectfully submitted that these claims are also allowable over the '478 patent.

New claim 26 depends directly from amended claim 15. As discussed hereinabove, amended claim 15 is not anticipated or suggest by the '717 patent or the '478 patent. Therefore it is respectfully submitted that new claim 26 is allowable for the reasons stated above.

Appl. No. 10/729,768
Amdt. dated June 29, 2005
Reply to Office Action mailed March 15, 2005

In view of the foregoing amendments and remarks, it is respectfully submitted that all claims pending in the application, namely claims 15-21 and 26, are in condition for allowance. If the Examiner should have any questions concerning this communication or feels that an interview would be helpful, the Examiner is requested to call Applicants' undersigned attorney at (631) 501-5713.

Respectfully submitted,


Dana A. Brussel
Reg. No. 45,717
Attorney for Applicants

Carter, DeLuca, Farrell & Schmidt, LLP
445 Broad Hollow Road - Suite 225
Melville, New York 11747
Tel.: (631) 501-5713
Fax: (631) 501-3526

Send correspondence to:
Chief Patent Counsel
Tyco Healthcare Group
150 Glover Avenue
Norwalk, CT 06856